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EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,912	ANTRIM ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,34,35 and 41-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,34,35 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is a response to Applicant's amendment submitted October 7, 2009, wherein claims 1, 2, 4, 34, 35, and 41-43 are amended.

Claims 1, 2, 4, 34, 35, and 41-43 are pending and are examined on the merits herein.

In view of Applicant's amendment submitted October 7, 2009, the rejection of claims 1, 2, 4, 34, 35, and 41-43 under 35 U.S.C. 112, second paragraph, as being indefinite with respect to the identity of "said mixture" and "said saccharide" is withdrawn.

The following rejections of record are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 34, 35, 41, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Saleeb (US 5,972,395, October 25, 1999, of record) as evidenced by Tate & Lyle (Maltodextrins & Corn Syrup Solids, of record).

Saleeb teaches a product prepared by extruding a mixture of glucose, maltose, maltotriose, mannose, sugar alcohols, adipic acid, citric acid, or malic acid, or a combination thereof; and high maltose corn syrup solids and/or 5-20 DE maltodextrin.

The extrusion may be carried out at temperatures up to 190°C. [claims 1-10]. As evidenced by Tate & Lyle, 5 DE maltodextrin contains dextrose (about 1%) along with other oligosaccharides, 88% of which are DP11+ or higher. Thus, citric acid along with dextrose and other malto-oligosaccharides which are starch hydrolysates and have DP of 5 or more were extruded. The "additional saccharide" could be any of the oligosaccharides present in the mixture. Although Saleeb does not teach whether the product contains a majority of 1,4-bonds as well as some 1,2- and 1,3-bonds, the product is made by the same process as is recited in the instant claims, so the product should be the same as that of the instant claims.

Response to Arguments

Applicant questions whether the above rejection is a 102 rejection or a 103 rejection because two references are presented. The rejection is a 102 rejection over Saleeb, and the Tate & Lyle reference is presented in order to illustrate that, as is known in the art, maltodextrin and corn syrup solids are comprised of a mixture of oligosaccharides of different degrees of polymerization.

Applicant argues that there is no express teaching of derivatization by Saleeb. This argument is not persuasive because Saleeb teaches extrusion of a mixture of saccharides in the presence of an acid, at a temperature which is described in the instant specification as being appropriate for the preparation of saccharide-derivatized oligosaccharides (page 10, 25°C-220°C). Thus, Saleeb teaches a product which is prepared by the same process as is recited in the instant claims and so the product should be the same as that of the instant claims. Since the Office does not have the

facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Applicant questions whether Saleeb teaches extrusion of a mixture containing a saccharide product which comprises at least 50% glucose. By the examiner's interpretation, the instant claims require an extrusion reaction product of a mixture of: (1) a saccharide product having a DP of 1-4 and comprising at least 50% dextrose; (2) a mixture of malto-oligosaccharides having a DP of 5 or more; (3) a starch hydrolysate; and (4) an additional saccharide. A starch hydrolyzate is a product resulting from the hydrolysis of starch, and encompasses malto-oligosaccharides and glucose. The additional saccharide could be considered any saccharide, but especially dextrose as recited in claim 41. Thus, the mixture which is subject to extrusion reaction contains, at minimum, glucose and malto-oligosaccharides having a DP of 5 or more. There is no limitation placed on the amount of glucose as a percentage of the total mixture which is subject to extrusion.

There is significant overlap between the products or mixtures recited in claim 1. For example, any or all of the "saccharide product having a DP of 1-4," the "additional saccharide," or the "starch hydrolyzate" could be glucose. The claims require an extrusion product of a mixture of all of these (along with malto-oligosaccharides). Thus, the glucose present in Saleeb's mixture can be considered part of the "saccharide

product," the "additional saccharide," and the "starch hydrolyzate." Saleeb teaches extrusion of a mixture of saccharides which includes glucose. Claim 1 requires a "saccharide product" which is at least 50% glucose, but does not require a particular percentage of the total mixture to be glucose. Thus, Saleeb's glucose could be considered the "saccharide product," which is at least 50% glucose. Saleeb's glucose could also be considered the starch hydrolyzate or the additional saccharide, as set forth above. Thus, it is considered that Saleeb's mixture contained a saccharide product which was at least 50% glucose. For these reasons, the rejection is maintained.

Claims 1, 2, 4, 34, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Porzio (US 5,603,971, February 18, 1997, of record) as evidenced by Tate & Lyle (Maltodextrins & Corn Syrup Solids, of record).

Porzio teaches a process wherein 10 DE maltodextrin, 42 DE corn syrup solids, and 0.5 wt% citric acid were extruded at 300°F (about 149°C). Typically, the temperature will be up to 320°F (about 160°C). The maltodextrin and corn syrup solids (starch hydrolyzates) comprise a variety of oligosaccharides, including dextrose and those which have DP of 5 or greater, as evidenced by Tate & Lyle. The "additional saccharide" could be any of the oligosaccharides present in the mixture. Although Porzio does not teach whether the product contains a majority of 1,4-bonds as well as some 1,2- and 1,3-bonds, the product is made by the same process as is recited in the

instant claims, and so the product should be the same as that of the instant claims. Thus, the claims are anticipated.

Response to Arguments

Applicant's arguments are the same as those addressed above for the Saleeb reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 34, 35, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Okhuma (US 5,358,729, October 25, 1994, of record).

Okhuma teaches a product which was prepared by extrusion of corn starch in the presence of hydrochloric acid [column 14, Experimental Example 1]. Characteristics of the products prepared are shown in Table 4. Sample No. 1, for example, contains 53.6% of 1,4-bonds and also contains 1,3- and 1,2-bonds. A different product had 62.3% of 1,4-bonds, as well as 1,2- and 1,3-bonds [Table 7, first entry].

Response to Arguments

Applicant argues that Okhuma does not use a starch hydrolyzate or a product including 50% dextrose as the starting material, and that Okhuma does not suggest addition of "additional" saccharide to the hydrolyzed starch. This argument is not

persuasive because the claims are drawn to a product prepared by extrusion of various saccharides, not the method of preparing it. Okhuma's product is a mixture of dextrins and contains the linkages as recited in claim 1. Thus, Okhuma's product appears to be the same as one prepared by the process recited in claim 1. The extrusion reaction is expected to result in bond breakage (starch hydrolysis) and new bond formation, and it is unclear how the addition of dextrose, as recited in amended claim 1, would affect the structure of the final product. Applicant mentions only that the dextrose serves as a processing aid. Furthermore, it is noted that no particular amount of dextrose or saccharide product is required by the claims. Thus, the claims are seen to encompass products prepared by the extrusion of mixtures which contain very small amounts of dextrose. Even if the effect of dextrose on the structure of the final product was clear, products prepared with very small amounts of dextrose would be very difficult to distinguish from Okhuma's product, since hydrolysis of starch and thus liberation of small oligosaccharides is expected to occur during Okhuma's process, producing a reaction mixture which contains large and small oligosaccharides. Okhuma's product appears to be the same as the claimed product for the reasons set forth above. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 1, 2, 4, 34-35, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyers (US Patent 5,518,739, of record).

Meyers teaches Fibersol, a maltodextrin derivatized with dextrin via glycosidic linkages such as α-1,6, β-1,2, β-1,3 and β-1,6 (col.3, lines 22-24). As recognized by Applicant in the declaration of Dr. Mungara submitted August 7, 2007 and in the response submitted November 14, 2008, Fibersol has 51.5% of 1,4-bonds and is digested by mammalian enzymes more slowly than glucose.

Response to Arguments

Applicant's arguments were addressed previously.

Claims 1, 2, 4, 34, and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Fouache et al. (US Patent 6,630,586, of record).

Fouache et al. disclose maltodextrin derivatized with dextrin via glycosidic linkages such as α-1,6 and α-1,4 (claim 1). Fouache et al also disclose maltodextrin derivatized with dextrin via glycosidic linkages such as 1-2, 1-3, 1-4, and 1-6 (Co1.8, Tables I and II). Products having 50% or 95% of 1,4-linkages are exemplified [column 8, Table I]. The product having 50% of 1,4-linkages also had 10% each of 1,2- and 1,3-linkages. As discussed above, it is not clear whether "extrusion" will necessarily result in a product having 1,2- and 1,3-bonds and thus claims 1, 2, 4, 34, and 35 are anticipated by products D and E of Table I, which have 95% 1,4-bonds. Product C is disclosed by Fouche et al. as having 50% 1,4-linkages. Applicant's response submitted

November 14, 2008 indicates that the percentage of 1,4-bonds in the Nutriose product was experimentally determined to be 49.6% by Dr. Mungara, when multiple linkages are counted. Using the declaration of Dr. Mungara submitted August 7, 2007 (Table 2), the examiner added the percentages for all the 4-glc values for Nutriose, including the multiple linkages. 4-glc was indicated on page 4 of the declaration to be where a branch point existed at the 4-position. The result of that calculation was 55.7%, which is a majority. Thus, the claims are anticipated.

Response to Arguments

Applicant's arguments were addressed previously.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 34, 35, and 41-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stahl (WO 01/33973, May 17, 2001, human translation, of record).

Stahl teaches a modified carbohydrate made of a base body and a carbohydrate residue coupled therewith [abstract]. In example 1, maltodextrin was derivatized with glucose residues [pages 19-21 of human translation document]. Products obtained by derivatization of maltodextrin with glucose in the 1-2, 1-3, 1-4, or 1-6 position are

specifically claimed [claim 4], and are preferably obtained by the use of transglucosidase from *Leuconostoc mesenteroides* [claim 5].

Stahl does not teach the percentage of bonds which are 1,2-, 1,3-, 1,4-, or 1,6-bonds. However, since Stahl's product is a derivatized maltodextrin, which is has 1,4-bonds, and because Stahl et al. teaches that the product of Example 1A is digestible [claim 1 and Figure on page 31], the skilled artisan would expect that Stahl's product contains a majority of 1,4-bonds. Further, Stahl provides guidance for the desirable characteristics of the product, glucose release [claim 1], and provides guidance for the use of other enzymes [page 17 and 18], and for variation of process conditions [page 19-25]. Thus, the skilled artisan would have motivation and guidance to optimize process conditions to obtain a product with moderated glucose release.

Response to Arguments

Applicant's arguments were addressed previously.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
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